REMARKS

Claim Status

Claims 1, 3, 5-22, 24-26, and 28-36 are pending in the present application.

Claims 1 and 26 are amended to characterize a select embodiment. Support may be found on page 10, lines 19 *etc.*

Claims 2, 4, 23, and 27 are cancelled without prejudice.

These changes do not involve any introduction of new matter. Consequently, entry of these changes is respectfully requested. No additional claims fee is believed to be due.

Rejection Under 35 U.S.C. §102

Claims 1, 3, 24, 26, and 32 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/0082219 to Warren *et al.* ("Warren"). Claims 1 and 26 have been amended to recite that the skin care composition is in the form of an emulsion. The Office acknowledges that Warren "does not disclose an emulsion or a composition comprising a phytosterol." Therefore, the rejection is now believed to be moot.

Rejection Under 35 U.S.C. §103(a)

Claims 4, 5, and 35 are rejected under 35 U.S.C. § 103(a) over Warren in further view of U.S. Patent 5,547,677 to Wright ("Wright"). Warren may not be used to preclude patentability according to the provisions of 35 U.S.C. §103(c). The present application, serial number 10/780,267, and U.S. Patent Publication No. 2003/0082219 to Warren *et al.* were, at the time the invention of the present application was made, owned or subject to an obligation of assignment to The Procter and Gamble Company. The rejection is traversed as Wright does not teach or suggest the all the limitations present in Claims 4, 5, and 35.

Claim 30 is rejected under 35 U.S.C. § 103(a) over Warren in further view of U.S. Patent No. 4,390,532 to Stuttgen *et al.* ("Stuttgen"). As presented above, Warren may not be used to preclude patentability according to the provisions of 35 U.S.C. §103(c). The rejection is traversed as Stuttgen does not teach or suggest the all the limitations present in Claim 30.

Claims 28 and 29 are rejected under 35 U.S.C. § 103(a) over Warren in further view of U.S. Patent No. 6,187,327 to Stack *et al.* ("Stack"). As presented above, Warren may not be

used to preclude patentability according to the provisions of 35 U.S.C. §103(c). The rejection is traversed as Stack does not teach or suggest the all the limitations present in Claims 28 and 29.

Claims 32-34 are rejected under 35 U.S.C. § 103(a) over Warren in further view of U.S. Patent No. 5,091,171 to Yu *et al.* ("Yu"). As presented above, Warren may not be used to preclude patentability according to the provisions of 35 U.S.C. §103(c). The rejection is traversed as Yu does not teach or suggest the all the limitations present in Claims 32-34.

Claims 1-5, 21, 23-24, 265 and 28-29 are rejected under 35 USC § 103(a) over U.S. Patent No. 6,284,802 to Bissett et al. ("Bissett"). In support for the rejection, the Office repeats its previously presented argument.

> Bissett et al. discloses the use of vitamin B3 compounds in skin care compositions. (Column 33, claim 3). Example 1 discloses a composition with 2% niacinamide, a vitamin B3 compound. (Column 30, lines 1-5; Column 16-17, section titled "Vitamin B3 compounds"). Water, glycerin and silicone fluids are disclosed in emulsions and are considered carriers. (Example 2). Hexamidine is disclosed as useful as an antimicrobial adduct. (Column 23, line 45-55).

The Office concedes that "Bissett does not exemplify a composition comprising hexamidine." The Office concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a skin care composition comprising hexamidine, and vitamin B3 and additional ingredients such as peptides, additives claimed in claim 3, and tocopherol acetate since all ingredients are well known for their use in skin care preparations and useful for compositions for skin care as disclosed in Bissett et. al." Applicant traverses the rejection on several grounds. Applicant continues to assert, even in light of the Office's comments in the March 27, 2009, Office Action, that the combination of hexamidine and vitamin B_3 yields unexpected and unappreciated results related to the regulation of mammalian keratinous tissue. A declaration was previously submitted under 37 C.F.R. §1.132 from Rosemarie Osborne, Ph.D., in support of the assertion of unexpected results.

First, the Office has failed to give proper weight and consideration to the declaration. The Office argues that "the results presented in the declaration merely concern the activation of various genes in *in vitro* culture and the speculation that these genes may produce a beneficial effect *in vivo* for the combined composition when administered to the skin. Absent the demonstration of actual therapeutic effect, this example is not persuasive to demonstrate actual unexpected results for the claimed compositions." Applicant previously pointed to the

declaration of Dr. Osborne as evidence that skin cultures are accepted as surrogates for natural human skin. The Office inappropriately disregards the genomics data and argues that "the observation in gene activation, in the absence of any evidence tying these genes to the desired biological effects, is not persuasive to demonstrate unexpected results for a combination that activates these genes." *Office Action of March 27, 2009*. The Office's explanation is without basis. There is no requirement that the unexpected result need be tied to "a specific observable effect." Applicant is unaware of any requirement that the unexpected result must be of the Examiner's choosing. To the contrary, "obviousness is determined by the totality of the record including, in some instances most significantly, the evidence and arguments proffered during the give-and-take of ex parte patent prosecution." *In re Chu*, 66 F.3d 292, 299 (Fed. Cir. 1995). Applicant asserts that the genomics data as provided in the declaration has not been fully considered by the Office.

Second, the Office argues that "the instant claims claim an extremely broad range of concentrations of the active ingredients, from about 0.0001% to about 25%. The experiments undertaken in the declaration are not sufficient to demonstrate a synergistic effect over such as broad range of concentrations and in every ratio that is included within the broad scope of the claims." In effort to advance prosecution, Applicant previously amended the claims such that the Office's assertion of the claims covering "an extremely broad range of concentrations" is believed to be moot. The Office now presents that "the declaration is not seen to disclose unexpected results over any ranges at all." Clearly, this statement lies at the heart of the obviousness determination. The Office finds no evidence of an unexpected result in the declaration. In light of the argument on record, Applicant asserts that sufficient evidence exists.

Third, the Office continues to make clear that it is looking for a particular unexpected result – namely, "the actual practical effect." Again, Applicant is unaware of any requirement that the unexpected result must be of the Examiner's choosing. Furthermore, Applicant asserts that the Office has failed to apply the appropriate case law in its review of obviousness. Case law states, "That a claimed novel compound possesses a certain advantageous activity which is not in fact possessed by a prior art compound is itself evidence of the nonobviousness of the subject matter as a whole." *In re Albrecht*, 514 F.2d 1389, 1396 (C.C.P.A. 1975). The Office has disregarded the genomic activity presented in the Declaration. The Office has provided no evidence that the prior art possessed the activity. As stated by *Albrecht*, this is evidence of nonobviousness. In light of the declaration and the guidance of *Albrecht*, Applicant asserts that the claimed subject matter is patentably distinct over the cited reference.

Fourth, Applicant further asserts that the declaration demonstrates the patentability of the claimed invention as understood from the directives of the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2D 1385 (2007). Throughout its decision, the Supreme Court emphasized the importance of "predictability" in the determination of obviousness. For example, the Supreme Court stated:

- "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable result."
- "The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result."
- "[A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions."

These passages illustrate a common theme in the Supreme Court's analysis of obviousness - predictability is the hallmark of obviousness. Dr. Osborne's declaration evidences the unpredictability of the combination of hexamidine and vitamin B3 - namely, through the synergistic regulation of genes that are fundamental to processes for regulating the condition of mammalian keratinous tissues such as skin. Applicant asserts that the claims are patentably distinct over the cited references.

Applicant request reconsideration of the declaration in light of the discussion presented above. Withdrawal of the rejection and allowance of the claims is respectfully requested.

Claim 25 is rejected under 35 USC § 103(a) over Bissett further in view of U.S. Patent Publication No. 2003/0176366A1 to Castiel et al. ("Castiel"). The Office relies on Castiel to teach a composition comprising ascorbyl glucoside. The Office concludes that the combination of Bissett and Castiel would have been obvious to one of ordinary skill in the art at the time the invention was made. Castiel does not address the combination of hexamidine and the vitamin B3 compound and, therefore, does not resolve the deficiencies presented above in regard to Claim 1 (from which Claim 25 depends).

Claims 1-5, 23, 24, 26-29, 31, and 36 are rejected under 35 USC §103(a) over U.S. Patent No. 6,589,514 (hereinafter "Jensen") in view of Flick et al. ("Flick")(Cosmetic Additives – An Industrial Guide, Pages 647-648, 652; PTO-892) further in view of Gensler et al. ("Gensler")(Nutrition and Cancer, 29(2), 157-162; PTO-892), and JP2002212053 to Oblong et

al. ("Oblong"). In support of this rejection, the Office combines the teachings of Jensen, Flick, Gensler, and Oblong. The cited references have been discussed previously by both the Office and Applicant. The Office relies on Jensen to teach a hexamidine composition. The Office concludes:

> It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, vitamin B3, panthenol, a-tocopherol acetate and a carrier because Jensen et. al. discloses skin care compositions comprising a-tocopherol acetate, hexamidine and discloses panthenol in skin care compositions and Flick et. al. discloses panthenol and a-tocopherol acetate as commercially available cosmetic additives and Gensler et. al. discloses that topical application of niacinamide and a-tocopherol can contribute to protection against UVB rays and Oblong et. al. discloses the beneficial effects of niacinamide such as regulating visible and tactile discontinuities of the skin. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All ingredients in the instant composition are well known in the prior art for use in skin care compositions with various beneficial effects. The combination of said ingredients results in a topical combination with expected results. Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and a-tocopherol in skin care compositions would have had beneficial effects such as moisturizing, maintenance of keratinization, protection against wrinkles and protection from UVB rays.

Applicant traverses the rejection on two grounds. First, a *prima facie* case of obviousness has not been established. Second, even if a *prima facie* case was established, the obviousness argument is overcome by the showing of unexpected results. Therefore, the claimed invention is patentably distinct and that the rejection should be withdrawn.

Applicant again asserts that a *prima facie* case of obviousness has not been established. As previously argued, the composition of Gensler is vastly different from the one proposed by the Office via Jensen. The combination of Jensen and Gensler is not obvious because Gensler discloses applying a solution of acetone and nicotinamide to mice. *See* pg. 157, 2nd col., last paragraph. Applicant asserts that a skilled artisan will readily recognize that acetone is not "a dermatologically acceptable carrier" as is required by Claim 1.

The Office rejected Applicant's argument. The Office presents, "[T]he use of various topically acceptable carriers, and the formulation of a known active ingredient in a known carrier is well within the ordinary and routine level of skin in the art." *Office Action of March 27, 2009.* The Office concludes, "One of ordinary skill in the art would reasonably have expected success

because this process of routine optimization is part of the ordinary and routine level of skill in the art." *Office Action of March 27, 2009.*

Applicant highlights two issues with the Office's reasoning. First, the reasoning is conclusory. The Office bases the reasonable expectation of success in combining Gensler and Jensen and on routine optimization. The Office points to "Remington: The Science and Practice of Pharmacy" ("Remington") in support of the optimization argument. The Office states that Remington teaches "various topical carriers . . . can be optimized for delivering a specific agent to treat a specific disease state." Remington actually states that an "ointment base functioning as a drug vehicle should be optimized for a specific drug." Remington merely provides a vague and rather obvious directive that an ointment should be optimized for the particular drug being delivered. Remington provides no guidance on how to actually achieve this in the case of Gensler and Jensen.

Second, the references cited and the Office's rationale do not address whether a reasonable expectation of success of the proposed combination exists such that the proposed combination yields no change in their respective functions of the references. Again, Gensler is directed to a simple solution of niacinamide in acetone that was shown to "prevent systemic immunosuppresion and skin tumorigenesis induced by UVB irradiation." *Gensler, p. 161.* The Office is combining the Gensler teachings of nicotinamide to the Jensen carrier comprising *Morinda citrifolia* fruit juice, purified water, cyclomethicone, hydrogenated polyisobutene, cetyl alcohol, glycerin, *Morinda citrifolia* seed oil, glyceryl stearate, myristyl myristate, octyl palmitate, PEG-40 stearate, vegetable oil, and the other optional ingredients. *Jensen, Example 2.* Case law suggests and the MPEP states, "A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art." *See* MPEP § 2143.02 (emphasis added); see also *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 1739 (2008)("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). The Office has not established that the prevention of "systemic immunosuppresion and skin tumorigenesis induced by UVB irradiation" of Gensler will be maintained when combined in the composition of Jensen. With the present combination, the Office has failed to present whether the proposed combination would change the respective functions of the references.

Related to this argument, the Office states, "Those of ordinary skill in the pharmaceutical art routinely formulate useful active ingredients in dosage forms for delivery by different routes of delivery such as topical administration." *Office Action of March 27, 2009*. With regard to the Flick reference, the Office states that a skilled artisan is "one of ordinary skill in the arts in the cosmetic, pharmaceutical and skin care industry." *Office Action of March 27, 2009*. Applicant asserts that the Office has not clearly identified the level of ordinary skill in the art as required by *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) ("Under *§ 103*, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."). In support of this rejection alone, the Office uses varying skill levels (cosmetic, pharmaceutical and skin care industry versus pharmaceutical arts). Therefore, a *prima facie* case of obviousness has not been established due to the misapplication of the *Graham* factors.

Having disposed of Gensler, the rejection appears to be based upon the combination of Jensen and Oblong (as the Office's use of Flick is directed to teaching panthenol compounds and vitamin E). Applicant asserts that a *prima facie* case of obviousness has not been established. The Supreme Court state, "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007) quoting *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006). The Office has failed to provide reasoning or rationale to support the conclusion of obviousness. The Office argues that Jensen discloses skin care compositions comprising hexamidine and Oblong discloses the beneficial effects of niacinamide, yet provides no explanation of why Jensen should be combined with Oblong. Specifically, neither reference provides a rationale for the use of hexamidine. Jensen lists hexamidine as an optional ingredient in Example 2 (along with 14 other optional ingredients), but provides no teaching or suggestion as to why hexamidine is present. The Office provides no rationale for why hexamidine should be present in the proposed combination of Jensen and Oblong. The rejection appears to be based on the mere listing of hexamidine as an optional ingredient without the "articulated reasoning with some rational underpinning" as necessitated by the Supreme Court.

Even if a *prima facie* case was established, the obviousness argument is overcome by the showing of unexpected results and the unpredictability of the combination. The discussion of

unexpected results is presented above (in regard to the rejection based on Bissett) and is applicable to the present rejection. Therefore, the claimed invention is patentably distinct and the rejection should be withdrawn.

Claim 26 comprises elements (a) and (b) from Claim 1 and further includes the limitation of a panthenol compound. The Office states that Jensen discloses the use of panthenol in a skin care composition. The Office further relies on Flick for teaching the role of panthenol in skin care products. However, Flick does not address the combination of hexamidine and the vitamin B3 compound. Therefore, the arguments presented above with regard to Claim 1 are applicable to Claim 26.

Claims 2-5, 23, 24, 27-29, 31, and 36 – These claims depend from and contain all the limitations of either Claim 1 or Claim 26. Since Claims 1 and 26 are patentably distinct in light of the arguments presented above, the claims dependent therefrom are also patentably distinct.

Claims 21-24 are rejected under 35 USC §103(a) over Jensen in view of Gensler, Oblong, and PCT Publication WO 00/67722 to Mammone ("Mammone"). In support of the rejection, the Office states, "Mammone et al. discloses the use of N-acetyl glucosamine in skin care composition used for exfoliation and moisturization." The Office concludes that the combination of Jensen, Gensler, Oblong, and Mammone would have been obvious to one of ordinary skill in the art at the time the invention was made. Mammone does not address the combination of hexamidine and the vitamin B3 compound and, therefore, does not resolve the deficiencies presented above in regard to Claim 1 (from which Claims 21-24 depend).

Claim 25 is rejected under 35 USC §103(a) over Jensen in view of U.S. Patent Publication No 2003/0176366A1 to Castiel *et al.* ("Castiel") and Oblong. The Office relies on Castiel to teach a composition comprising ascorbyl glucoside. The Office concludes that the combination of Jensen, Oblong, and Castiel would have been obvious to one of ordinary skill in the art at the time the invention was made. Castiel does not address the combination of hexamidine and the vitamin B3 compound and, therefore, does not resolve the deficiencies presented above in regard to Claim 1 (from which Claim 25 depends).

Response to Double Patenting Rejection

Claims 1-5, 23, 26, 31, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 11, 12, and 20 of copending Application No. 10/841,193. Since the rejection is provisional as being based upon an application, Applicant requests that the rejection be held in abeyance until such time that Application No. 10/841,193 is allowed and issues as a patent.

Claims 1-5, 21-24, 31, 32, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-13, and 18 of copending Application No. 10/977,848. Since the rejection is provisional as being based upon an application, Applicant requests that the rejection be held in abeyance until such time that Application No. 10/977,848 is allowed and issues as a patent.

Claims 1-2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 4-16 of copending Application No. 10/152,924. Since the rejection is provisional as being based upon an application, Applicant requests that the rejection be held in abeyance until such time that Application No. 10/152,924 is allowed and issues as a patent.

At the present time, the pending nonstatutory obviousness-type double patenting rejections are provisional. Case law makes clear that no further action is needed on these provisional obviousness-type double patenting rejections. *In re Mott*, 539 F.2d 1291, 1296 (C.C.P.A. 1976) ("Once the provisional [double patenting] rejection has been made, there is nothing the examiner and the applicant must do until the other application issues.").

CONCLUSION

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied reference(s). In view of the foregoing, it is requested that the Examiner reconsider and withdraw the rejections. Early and favorable action in the case is respectfully requested. Again, the Office is encouraged to contact the Applicant's representative should questions arise.

Respectfully submitted,

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